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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/507,145

09/08/2004

Ilaria Meloni

962-PCT-US

9082

7590

08/11/2006

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EXAMINER

BABIC, CHRISTOPHER M

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 08/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/507,145	Applicant(s) MELONI ET AL.	
	Examiner Christopher M. Babic	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 08 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>9/18/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the Claims

Applicant has cancelled originally presented claims 1-13 and added new claims 14-18. The following Office Action is in response to Applicant's response dated June 16, 2006.

Election/Restrictions

Newly added claims 14 is drawn to a diagnostic kit for MR-associated syndromes to work a method for the determination of the enzymatic activity of FALC4 protein in a biological sample.

Thus, Applicant's election of group VI is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "cold" in claim 14 is a relative term that renders the claim indefinite. The term "cold" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Malhotra et al. ("Identification and molecular characterization of acyl-CoA synthetase in human erythrocytes and erythroid precursors" Biochem J. 1999 Nov 15;344 Pt 1:135-43).

With regard to claim(s) 14, it is initially noted that the phrase --for MR-associated syndromes to work a method for the determination of the enzymatic activity of FACL4 protein in a biological sample-- is considered an *intended use* of the claimed **product** and does not incorporate a patentably distinct feature.

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Is it further noted that the method steps (a-c) are considered a set of instructions for the *intended use* of the claimed **product** and do not incorporate any patentably distinct features. Applicant is directed to *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) which states, "when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability."

Malhotra et al. teach a product comprising: a) lysis buffer (page 136, bottom column 2, for example); b) coenzyme agent A and ATP (page 137, column 1, paragraph 3, for example); and c) arachidonic acid (page 137, column 1, paragraph 3, for example). As submitted above, the term "cold" is a relative term that renders the claim indefinite (see above 35 U.S.C. 112). Thus, the teachings of Malhotra anticipate the claimed product.

With regard to claim 15, Malhotra teaches reduction agents (page 137, top column 1, for example).

With regard to claim 16, Malhotra teaches biological fluids (page 135, column 2, paragraph 3, for example). It is noted that the phrase "biological fluids" is not defined in the specification in any limiting manner. Thus, the teachings of Malhotra anticipate the claimed product.

With regard to claims 16 and 17, Malhotra teaches ¹⁴C-labeled arachidonic acid (page 137, column 1, paragraph 3, for example).

2. Claims 14-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakken et al. ("Identical subcellular distribution of palmitoyl-CoA and arachidonoyl-CoA synthetase activities in human blood platelets" *Biochem J.* 1989 Jul 1;261(1):71-6).

With regard to claim(s) 14, it is initially noted that the phrase --for MR-associated syndromes to work a method for the determination of the enzymatic activity of FACL4 protein in a biological sample-- is considered an *intended use* of the claimed **product** and does not incorporate a patentably distinct feature.

Is it further noted that the method steps (a-c) are considered a set of instructions for the *intended use* of the claimed **product** and do not incorporate any patentably distinct features. Applicant is directed to *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983) which states, "when descriptive material is not functionally related to the substrate, the descriptive material will not distinguish the invention from the prior art in terms of patentability."

Bakken et al. teach a product comprising: a) lysis buffer (page 72, column 1, paragraph 2, for example); b) coenzyme agent A and ATP (page 72, column 2, paragraph 3, for example); and c) arachidonic acid (page 72, column 2, paragraph 3, for example). As submitted above, the term "cold" is a relative term that renders the claim indefinite (see above 35 U.S.C. 112). Thus, the teachings of Bakken anticipate the claimed product.

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With regard to claim 15, Bakken teaches reduction agents (page 72, column 2, paragraph 3, for example).

With regard to claim 16, Bakken teaches biological fluids (page 72, column 1, paragraph 2, for example). It is noted that the phrase "biological fluids" is not defined in the specification in any limiting manner. Thus, the teachings of Bakken anticipate the claimed product.

With regard to claims 16 and 17, Bakken teaches ^{14}C -labeled arachidonic acid (page 71, column 2, paragraph 1, for example).

Conclusion

Claims 14-18 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher M. Babic whose telephone number is 571-272-8507. The examiner can normally be reached on Monday-Friday 7:00AM to 4:00PM.

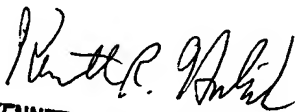
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Christopher M. Babic
Patent Examiner
AU 1637



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER

8/7/06